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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,252	09/21/1998	RONALD MARK EVANS	SALK1470-2	8370

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[REDACTED] EXAMINER

BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Offic Action Summary</b>	Application N .	Applicant(s)
	09/155,252	EVANS ET AL.
	Examiner Bridget E. Bunner	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 December 2002.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 16-20 and 27-45 is/are pending in the application.
- 4a) Of the above claim(s) 29-35 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 16,27,28,36,37,39-42 is/are rejected.
- 7) Claim(s) 17-20,38 and 43-45 is/are objected to.
- 8) Claim(s) 16-20 and 27-45 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>30</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                 |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Prosecution Application***

The Request for Continued Examination (RCE) filed on 25 October 2002 (Paper No. 27) under 37 CFR 1.114 based on parent Application No. 09/155,252 is acceptable and an RCE has been established. An action on the RCE follows.

### ***Status of Application, Amendments and/or Claims***

The amendments of 25 October 2002 (Paper No. 28) and 11 December 2002 (Paper No. 29) have been entered in full. Claims 29-45 are added and claims 16, 20, 27-29, and 33-35 are amended.

Newly submitted claims 29-35 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The previously examined method claims did not require a native PPAR- $\gamma$  or, by extension, a reporter construct that is activated upon binding of a native PPAR- $\gamma$ . Examination of claims 29-35 would thus require a significant extension of the search for the previously examined methods, resulting in an undue search burden on the examiner. Furthermore, claims to methods requiring a native PPAR- $\gamma$  (e.g., claim 29) are patentably distinct from previously examined methods requiring a chimeric PPAR- $\gamma$ /GAL4 construct, since the methods are directed to recognized divergent subject matter and require non-coextensive searches.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 29-35 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16-20, 27-28, and 36-45 are under consideration in the instant application.

***Withdrawn Objections and/or Rejections***

1. The objection to the specification regarding a missing abstract as set forth at pg 3 of the Office Action of 27 February 2002 (Paper No. 20) and pg 4 of the Office Action of 15 August 2001 (Paper No. 17) is *withdrawn* in view of the abstract submitted in the Response of 26 July 2002 (Paper No. 22).
2. The rejection of claims 16-20 and 27-28 under 35 U.S.C. § 112, first paragraph (enablement) as set forth at pg 3-6 of the Office Action of 27 February 2002 (Paper No. 20) and pg 5-7 of the Office Action of 15 August 2001 (Paper No. 17) is *withdrawn* in view of the Applicant's persuasive arguments (25 October 2002, Paper No. 28).

***Oath/Declaration***

3. The objection to the declaration regarding the issue of not identifying the post office address of each inventor is maintained and held in abeyance until allowable subject matter is identified (see the Office Action of 15 August 2001, Paper No. 17).

***Claim Objections***

4. Claims 17-20, 38, and 43-45 are objected to as being dependent upon a rejected base claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 16 and 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Marcus et al. (Proc Natl Acad Sci USA 90: 5723-5727, 1993).

Marcus et al. teaches method of testing a compound for its ability to regulate transcription-activating effects of the PPAR- $\gamma$  receptor by assaying for the changes in the level of luciferase reporter protein present as a result of contacting cells containing PPAR- $\gamma$  and a reporter vector with the compound. Marcus et al. discloses a PPAR- $\gamma$  receptor expression vector that comprises DNA encoding *Xenopus* PPAR- $\gamma$  (pg 5724, ¶ 1). Webster et al also teaches a reporter vector entitled, pHDX(x3)luc, that comprises a rat enoyl-CoA hydratase/3-hydroxyacyl-CoA dehydrogenase (HD) promoter, 3 tandem copies of the HD peroxisome proliferator-responsive element (PPRE), and a luciferase reporter gene (pg 5723, last ¶). Webster et al. discloses a second reporter vector, entitled pAOx(x2)luc, that comprises a rat fatty acyl-CoA oxidase (AOx) promoter, 2 tandem copies of the rat AOx PPRE, and a luciferase reporter gene (pg 5723, last ¶). Webster et al. teaches cotransfected COS-1 cells with the receptor expression vector and a reporter vector and contacting the cells with ciprofibrate, or Wy-14,643, wherein the substances caused an increase or decrease in the level of luciferase reporter protein (pg 5724-5725; pg 5726; Figures 1 and 6).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 36-37, and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster et al. (Cell 54:199-207, 1988) in view of Greene et al. (U.S. Patent 6,200,802).

Webster et al. teaches a method of testing a compound for its ability to regulate transcription-activating effects of estrogen and glucocorticoid receptors by assaying for the changes in the level of CAT reporter protein present as a result of contacting cells containing GAL4 chimeric estrogen/glucocorticoid receptors and a reporter vector with the compound (pg 200, col 2; Figure 2-3; pg 202, last ¶ of col 2 through 203). Webster et al. discloses GAL4 chimeric estrogen(ER)/glucocorticoid (GR) receptor expression vectors that comprise DNA that encodes amino acids 1-74 or amino acids 1-174 of the DNA binding domain of GAL4 and a region containing the hormone-binding domain of human ER or GR (pg 200, col 2; Figure 5). Webster teaches substituting the native DNA binding domain of PPAR- $\gamma$  with the DNA encoding the GLA4 DNA binding domain (pg 199-201). Webster et al also teaches a reporter vector that comprises rabbit  $\beta$ -globin promoter, two synthetic 17-mer GAL4 DNA binding sites, and a DNA segment that encodes the CAT reporter protein (pg 200, col 2; Figure 3(A)). Webster et al.

teaches cotransfected HeLa cells with the receptor expression vector and reporter vector and contacting the cells with hormones and anti-hormones wherein the substances caused an increase or decrease in the level of CAT reporter protein (pg 202-203; Figure 3(B)-3(C)).

Webster et al. does not teach a GAL4 chimeric PPAR- $\gamma$  receptor expression vector.

Greene et al. teaches the nucleic acid sequence and amino acid sequence of the human PPAR- $\gamma$  receptor (SEQ ID NOs: 1 and 2). Greene et al. also discloses several domains of PPAR- $\gamma$ , including the D domain or ligand binding domain (col 14; Figure 1).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the GAL4 chimeric receptor/reporter vector method for testing the transcription activation of a compound as taught by Webster et al. by utilizing the PPAR- $\gamma$  receptor as taught by Greene et al. The person of ordinary skill in the art would have been motivated to make that modification because PPAR- $\gamma$  is widely expressed in the human hematopoietic system (Greene et al., col 36-39) and the nuclear receptor subfamily to which the PPAR- $\gamma$  receptor belongs has been shown to regulate the transcription of key enzymes in fatty acid metabolism and may play a role in cancer cell proliferation and differentiation (Greene et al., col 2). The person of ordinary skill in the art reasonably would have expected success because similar methods were already being performed to discover the transcription activating effects of various compounds on receptors at the time the invention was made. Therefore, the claimed invention as a whole was clearly *prima facie* obvious over the prior art.

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***Conclusion***

No claims are allowable.

The art made of record and not relied upon is considered pertinent to applicant's disclosure:

Braselmann et al. Proc Natl Acad Sci USA 90: 1657-1661, 1993.

Allenby et al. Proc Natl Acad Sci USA 90 : 30-34, 1993.

Lehmann et al. J Biol Chem 270(22) : 12953-12956, 1995.

Harmon et al. Proc Natl Acad Sci USA 92 : 6157-6160, 1995.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

BEB  
Art Unit 1647  
February 21, 2003

*Elyabett C. Kummer*

ELIZABETH KUMMER  
PATENT EXAMINER

## Summary of Record of Interview Requirements

### **Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### **Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews**

#### **Paragraph (b)**

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### **37 CFR §1.2 Business to be transacted in writing.**

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner.  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### **Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.